













eSubmitter eCopies Quick Reference Guide

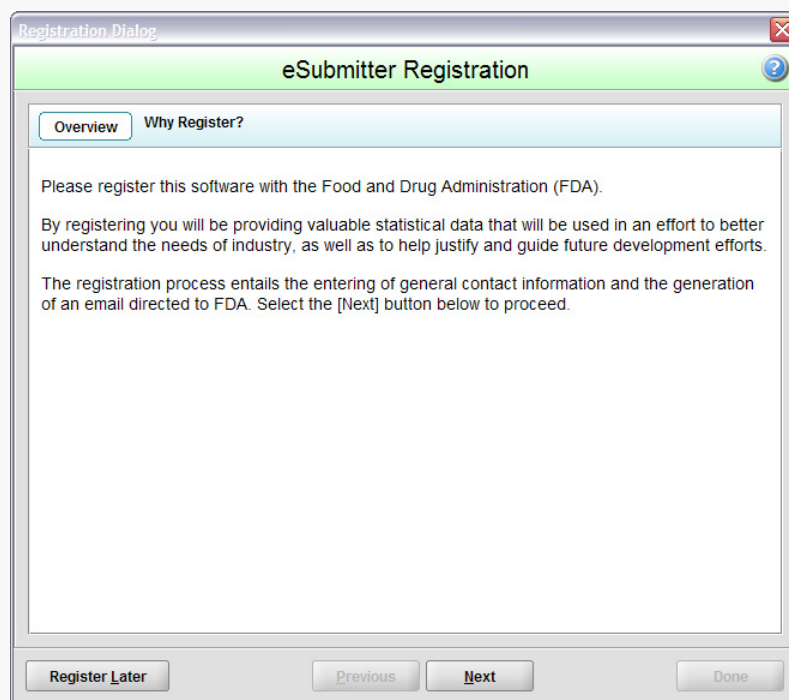
The Food and Drug Administration's Center for Devices and Radiological Health's (CDRH) MDUFA III eSubmitter eCopies tool allows for applicant to create an electronic copy (eCopy) that is consistent with the technical specifications.

eSubmitter Useful Steps

-  1. Create new submission
-  2. Open existing submission
-  3. Save submission
-  4. Simple view
-  5. Expert (outline) view
-  6. Home screen (return to the beginning at any time)
-  7. Navigation buttons for simple view
-  8. Process screen changes
-  9. Screen undo
-  10. Cut, Copy and Paste
-  11. Package submission
-  12. Help

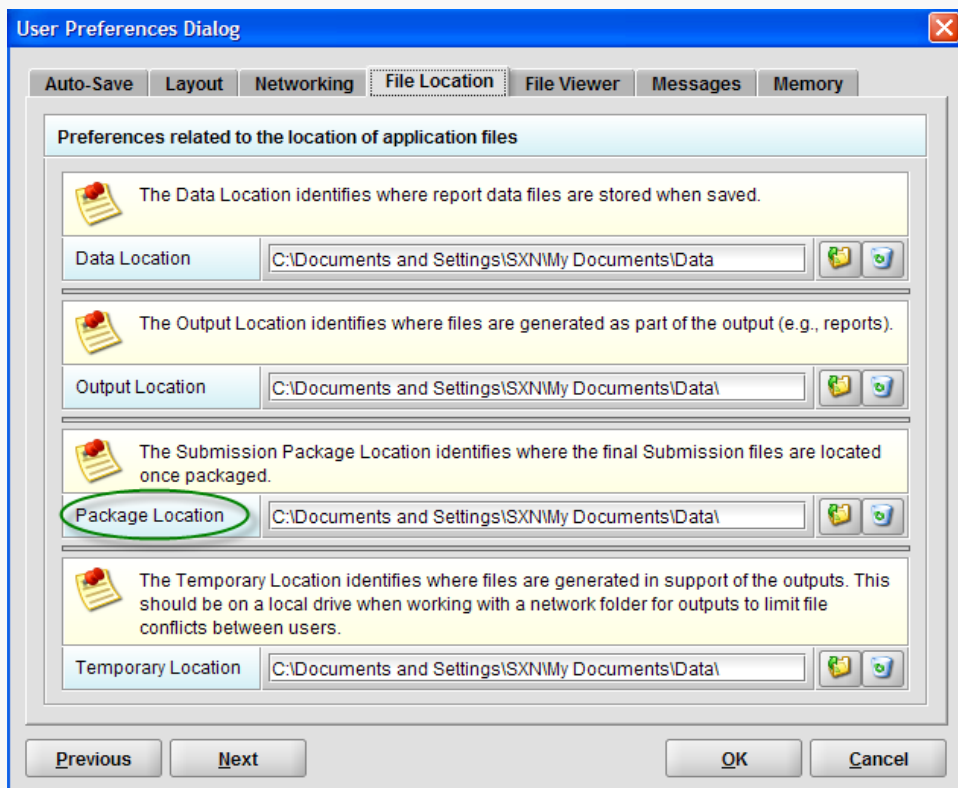
Initial Steps

1. An eSubmitter Registration window will be open. You can choose to register now or later registration information can be found at <http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM306936.pdf> on page 8.

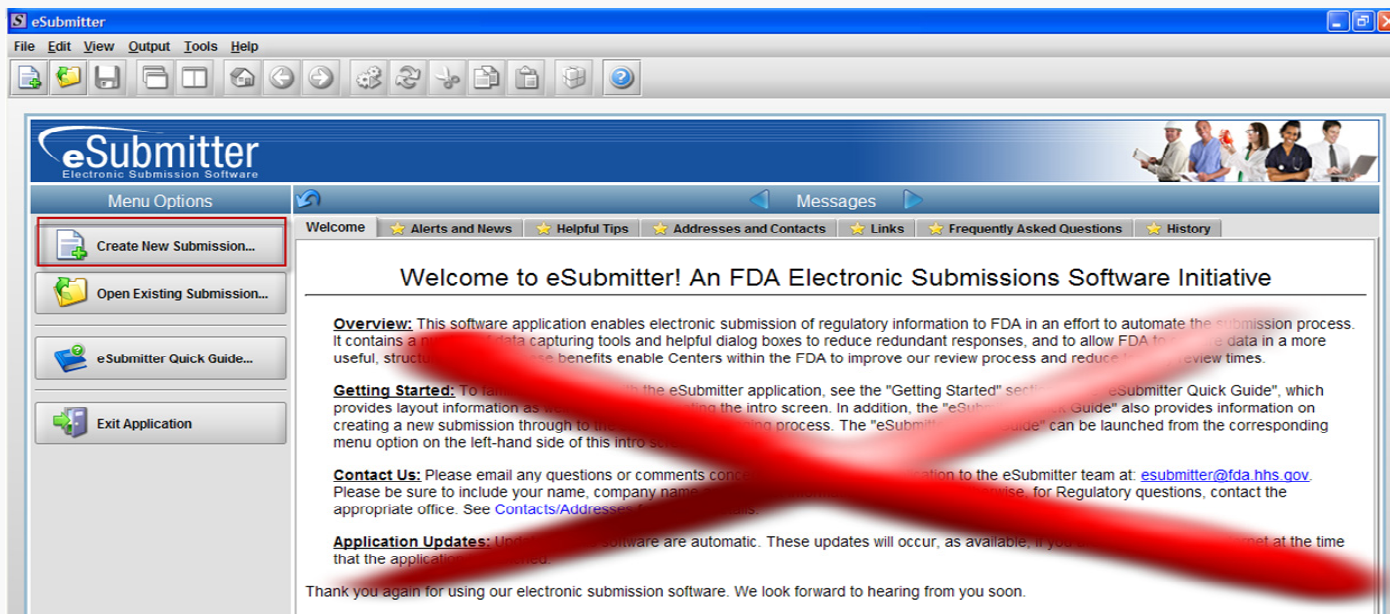


eSubmitter eCopies Quick Reference Guide

- Set the location where your file eSubmitter package will be saved on your local drive when you complete the process. This is done by going to File > Preferences > File Location. Then modify the Package Location field. Click OK when done.



- At the main screen, select the **Create New Submission** button in the left panel. Please disregard the welcome message as it does not pertain to eCopies.



eSubmitter eCopies Quick Reference Guide

4. Scroll down the list and choose CDRH: eCopies.

Name	Version	Version Date
CDRH: 806 Corrections and Removal Reporting	1.0	05/08/2012 09:58:42
CDRH: Complaint Reporting (Medical Device and Radiation Emitting Products)	1.0	05/08/2012 09:59:12
CDRH: eCopies	1.0	08/21/2012 03:55:47
CDRH: In Vitro Diagnostic Device - 510(k)	1.3	08/05/2012 08:17:43
CDRH: ISO13485	1.0	08/05/2012 08:18:30
CDRH: MedWatch Form 3500A (OMB No. 0910-0291)	1.0	08/05/2012 08:19:20
CDRH: Radiation Emitting Product (OMB NO. 0910-0025)	2.3	08/06/2012 11:36:7

5. Click Next to proceed.

6. Complete the **Descriptive Name** and **File Name** fields.

TIPS:

- The Descriptive Name will be the name that is referenced at the top of the eSubmitter screen as you continue through the process.
- File Name (.xml) field, allows you to create a name for your eSubmitter data file. (This is different than the eCopies output)
- File name will not accept periods, colons, question marks, angled braces, bar, tilde, asterisk, single/double quotes and forward or backward slashes.

Specify the Submission Descriptive and File Names

- Descriptive Name: Spinal System XYZ
- File Name (.xml): xyz

Additional Comments about this Submission

7. Click Create to proceed.

eSubmitter eCopies Quick Reference Guide

8. Determine the view that you want to work in. There is the Simple view and the Expert view.

The Simple view is the default, and it is shown below.

File Edit View Output Tools Help

Submission Name: 913 quick guide
Report Type: CDRH: eCopies

Last Modified: 09/13/2012 11:21:43 AM
Date Packaged:

Screen View Submission: eCopy Structure

eCopy Structure

The structure of an eCopy is highly dependent on the overall file size of the submission and can be organized using files and folders in one of the following ways:

1. Volume-based eCopy submission (generally recommended for large or complex submissions) - create either multiple volumes on one or more CDs/DVDs organized into folders containing each volumes associated files or create one PDF document for each volume.
2. Non-volume-based eCopy submission (generally recommended for small submissions) - create either one PDF document for each table of contents entry or create a single PDF document with bookmarks corresponding to the table of contents.

Please select the type that best describes your eCopy structure

☒ Non-Volume Based
☐ Volume Based

Some submissions may require files that should not or cannot be submitted in PDF format. These files can be submitted in their native format as long as they are placed in a zip file(s) under one of these subfolders.

1. Misc Files (e.g., videos, x-rays, machine-readable software source code) may be submitted in native formats such as, but not limited to: .gif, .tif, .jpg; .avi, .mpeg; .wmv; and .txt. In addition, for the purpose of streamlining the review process, FDA encourages you to also include Word copies of some of the documents or pieces of information provided in the main body of the eCopy as a PDF (e.g., labeling).
2. Statistical Data (e.g., statistical raw data, statistical analysis programs) may be submitted in their native format such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; XML; ASCII; Molfiles; and Excel.

Does your submission contain Misc Files or Statistical Data? Select all that apply.

☒ Misc Files
☐ Statistical Data

The Expert view has a left panel and may make it easier to navigate through the process. You

an change the view by clicking the Expert  icon at the top of the screen. The Expert

view is shown below. You can switch between the Simple and Expert views any time by

clicking between the Expert or Simple  icon which is next to the Expert icon.

The remaining slides will be shown in the Expert view.

File Edit View Output Tools Help

Submission Name: 913 quick guide
Report Type: CDRH: eCopies

Last Modified: 09/13/2012 11:21:43 AM
Date Packaged:

Outline

- Submission
- eCopy Structure
- Non-Volume Based
- Volume Based
- Attachments
- Statistical Data and Misc Files

Screen: eCopy Structure

eCopy Structure

The structure of an eCopy is highly dependent on the overall file size of the submission and can be organized using files and folders in one of the following ways:

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2. Non-volume-based eCopy submission (generally recommended for small submissions) - create either one PDF document for each table of contents entry or create a single PDF document with bookmarks corresponding to the table of contents.

Please select the type that best describes your eCopy structure

☒ Non-Volume Based
☐ Volume Based

Some submissions may require files that should not or cannot be submitted in PDF format. These files can be submitted in their native format as long as they are placed in a zip file(s) under one of these subfolders.

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2. Statistical Data (e.g., statistical raw data, statistical analysis programs) may be submitted in their native format such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; XML; ASCII; Molfiles; and Excel.

Does your submission contain Misc Files or Statistical Data? Select all that apply.

☒ Misc Files
☐ Statistical Data

eSubmitter eCopies Quick Reference Guide

9. Determine which type of eCopy structure you want to create and choose **Non-Volume based** or **Volume based** on the right side of the screen.

In addition, do you have non-PDF files to add? If so, then choose the **Misc Files** and/or **Statistical Data** folder, as applicable. All files in these sections must be part of a zip file.

File Edit View Output Tools Help

Submission Name: 913 quick guide
Report Type: CDRH: eCopies

Last Modified: 09/13/2012 11:21:43 AM
Date Packaged:

Outline

Submission

eCopy Structure

Non-Volume Based

Volume Based

Attachments

Statistical Data and Misc Files

Screen: eCopy Structure

eCopy Structure

The structure of an eCopy is highly dependent on the overall file size of the submission and can be organized using files and folders in one of the following ways:

1. Volume-based eCopy submission (generally recommended for large or complex submissions) - create either multiple volumes on one or more CDs/DVDs organized into folders containing each volume associated files or create one PDF document for each volume.
2. Non-volume-based eCopy submission (generally recommended for small submissions) - create either one PDF document for each table of contents entry or create a single PDF document with bookmarks corresponding to the table of contents.

Please select the type that best describes your eCopy structure

☒ Non-Volume Based
☐ Volume Based

Some submissions may require files that should not or cannot be submitted in PDF format. These files can be submitted in their native format as long as they are placed in a zip file(s) under one of these subfolders.

1. Misc Files (e.g., videos, x-rays, machine-readable software source code) may be submitted in native formats such as, but not limited to: .gif, .tif, .jpg, .avi, .mpeg, .wmv, and .txt. In addition, for the purpose of streamlining the review process, FDA encourages you to also include Word copies of some of the documents or pieces of information provided in the main body of the eCopy as a PDF (e.g., labeling).
2. Statistical Data (e.g., statistical raw data, statistical analysis programs) may be submitted in their native format such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; XML; ASCII; Molfiles; and Excel.

Does your submission contain Misc Files or Statistical Data? Select all that apply.

☒ Misc Files
☐ Statistical Data

10. Click the green right arrow in the top navigation panel to proceed to the next screen.

Depending on what combination you chose in the first screen, the next set of screens will differ.

Non-Volume Based

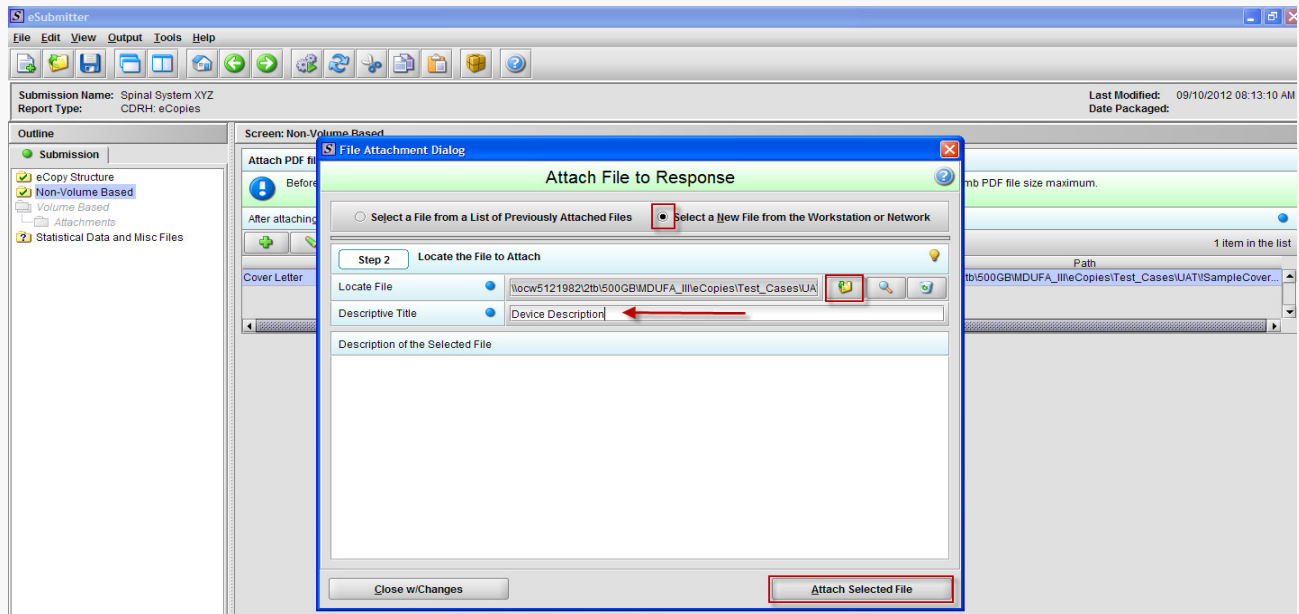
11. Add one file at a time by clicking onto the green plus sign.

The screenshot displays the eSubmitter application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Output", "Tools", and "Help". The toolbar contains various icons for file operations. The main area shows "Submission Name: Spinal System XYZ" and "Report Type: CDRH: eCopies". The "Outline" pane on the left lists "Submission", "eCopy Structure", "Non-Volume Based" (selected), "Volume Based", "Attachments", and "Statistical Data and Misc Files". The main content area is titled "Screen: Non-Volume Based" and contains instructions to attach PDF files, a warning about PDF size and content, and a note about sorting files. Below this is a table with columns "Title", "Name", "Date", "Size", and "Path", which is currently empty, showing "0 items in the list".

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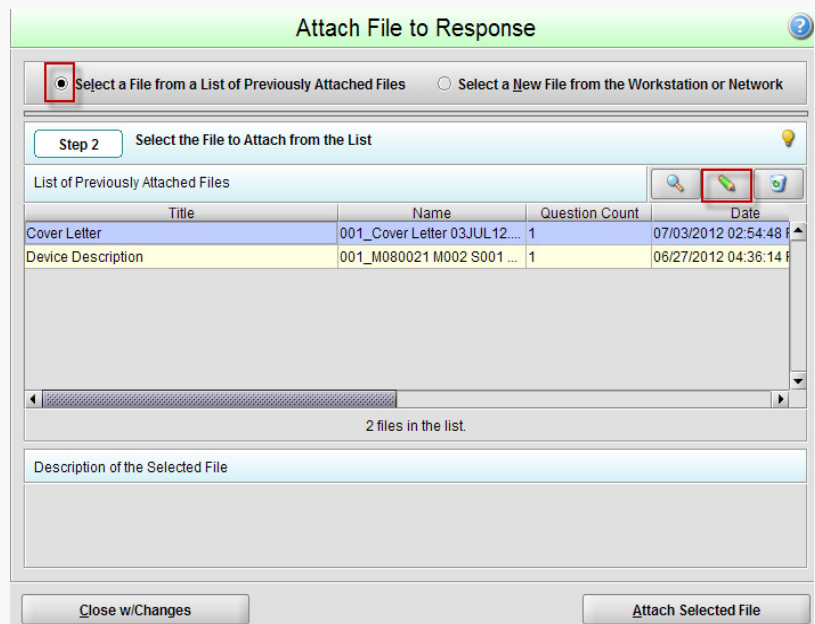
Non-Volume Based cont.

- The Attach File to Response window pops up. To add a new file, make sure the button entitled, "Select a New File from the Workstation or Network" is selected. Click the folder icon to navigate to and select the desired PDF. Then complete the Descriptive Title of that file. Click Attach Selected File at the bottom of the pop-up.



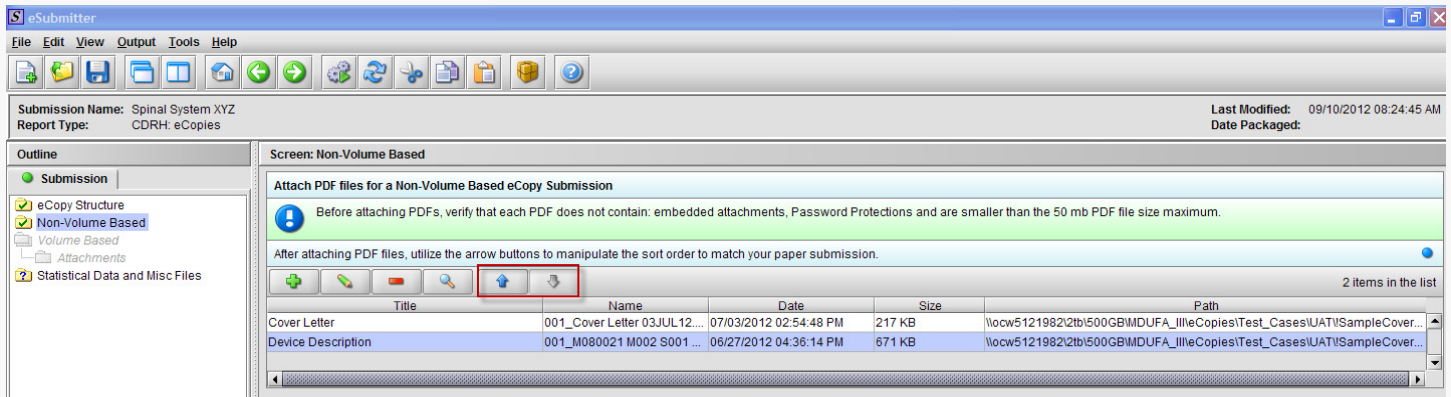
TIP: You can edit a PDF file entry in the same screen above by choosing the other button entitled, "Select a File from a List of Previously Attached Files." As you can see from the screen shot to the right this changes the options available, including the availability of an Edit icon.

- When done adding files, close the window by clicking Close w/Changes on the bottom left.



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14. You can sort your final list of files with the up and down arrow icons.

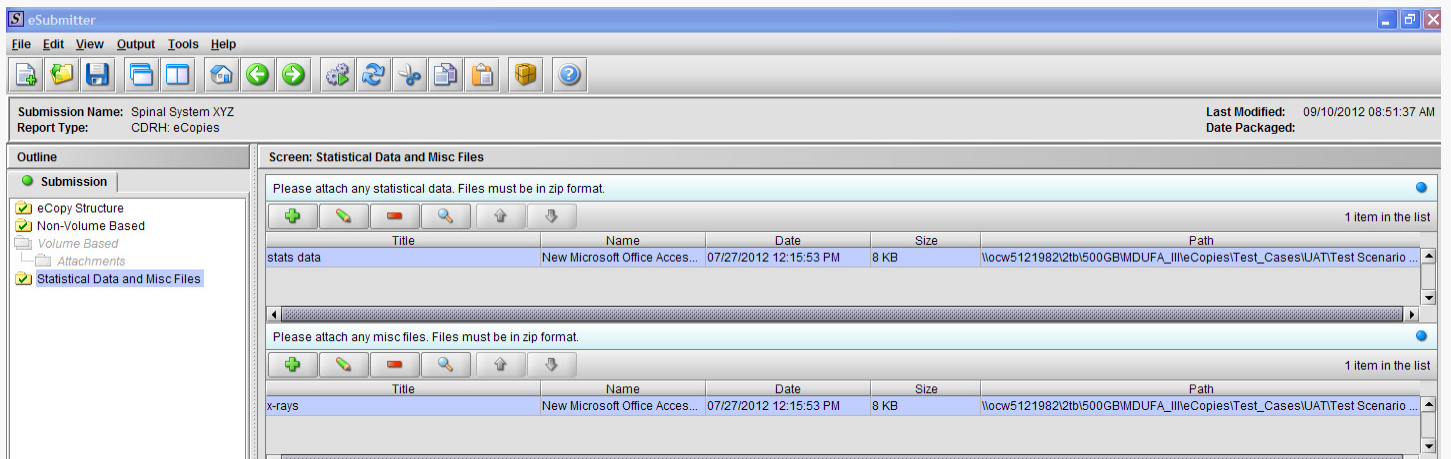


15. If, in the first screen, you had chosen the Misc Files and/or Statistical Data folders for non-PDF files, then proceed to the next step by clicking the green arrow at the top of the navigation section.



However, if you had NOT chosen one of these two folders, then you would have a message below your list of files instructing you to proceed to packaging your submission. Skip to #23 for packaging instructions.

16. The next screen shows the Misc Files and Statistical Data folders. However, only the folder(s) chosen in Step # 9 are enabled, as indicated by the green “+” button. If you did not choose one of the folders, then it would be a grayed-out “+” button, which prevents you from adding to that folder. As an example, the screen shot below shows that both folders were chosen.

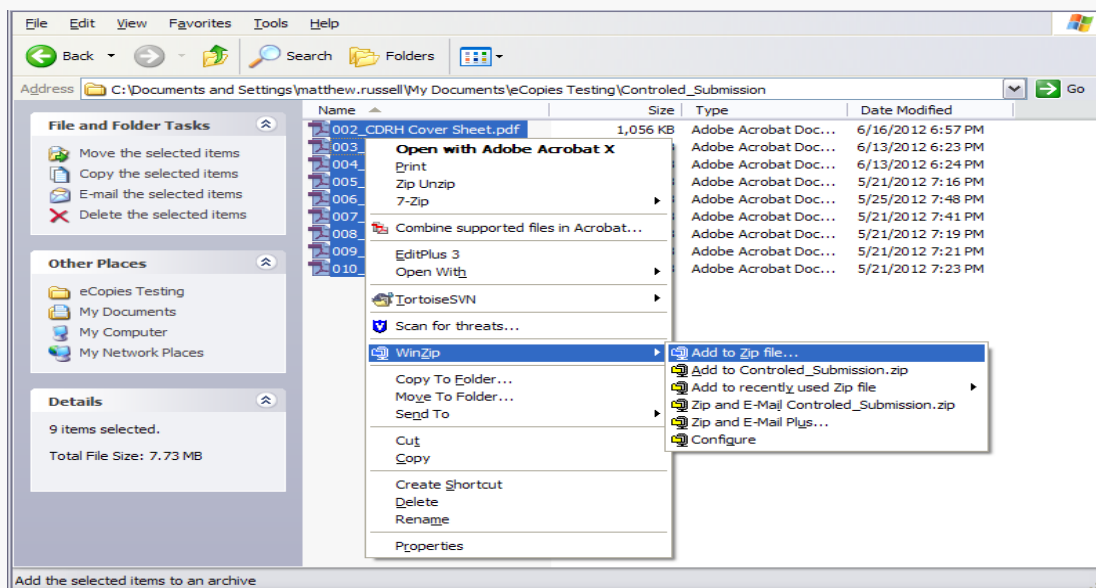


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Add the zip file(s) that contain non PDF files to each enabled volume. The steps for adding zip files are the same as for PDF files. There must be at least 1 zip file added to each enabled folder (in this example, both folders) or you cannot proceed to packaging the submission

Tip: To create a file utilizing WinZip, follow these steps;

- Create and name a new folder
- Identify and move all the files you wish to zip in the new folder
- Select all files
- Right click on the files
- A WinZip prompt will appear
- Click the "Add" button
- Zip file created

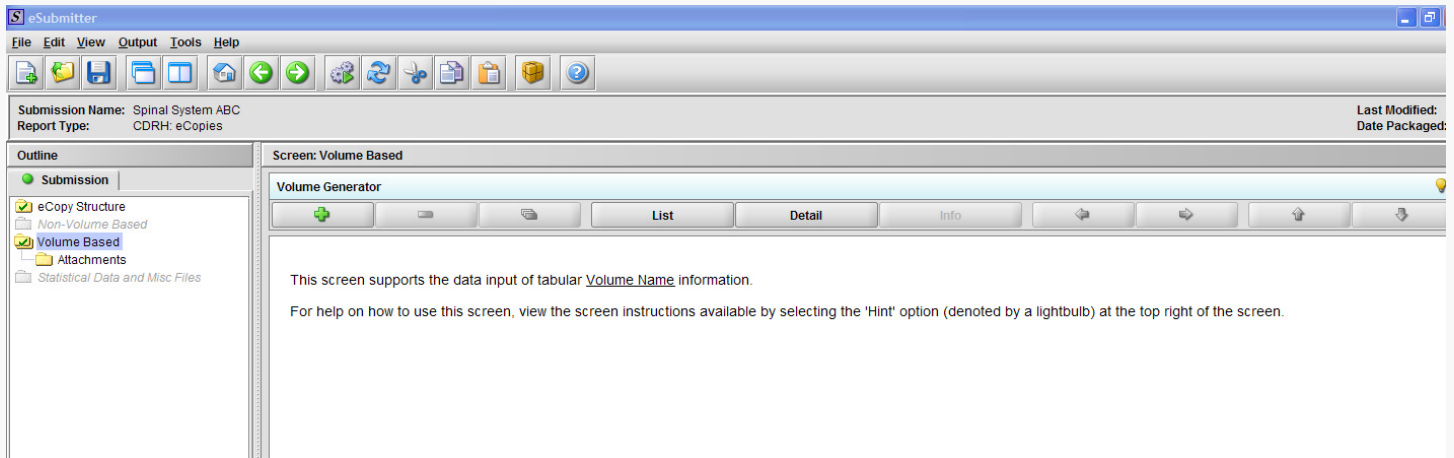


17. As per the message at the bottom of the screen, after adding all zip files, proceed to packaging your submission. Skip to #23 for packaging instructions.

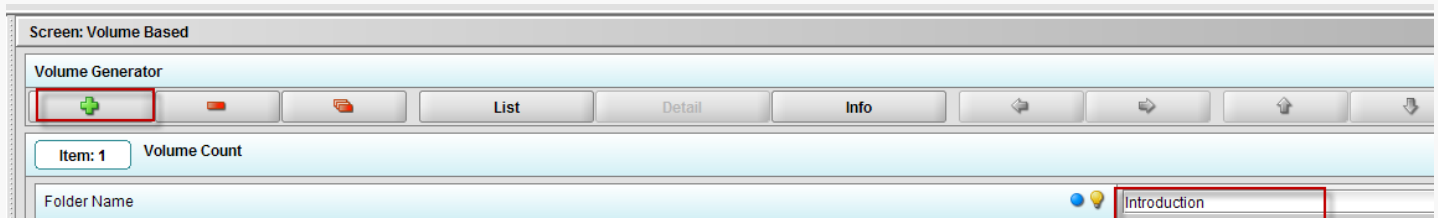
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Volume Based

18. If you selected a Volume Based submission, the screen below is what you will first see.



19. Add each volume name by clicking on the green “+” button and adding the Volume Name.



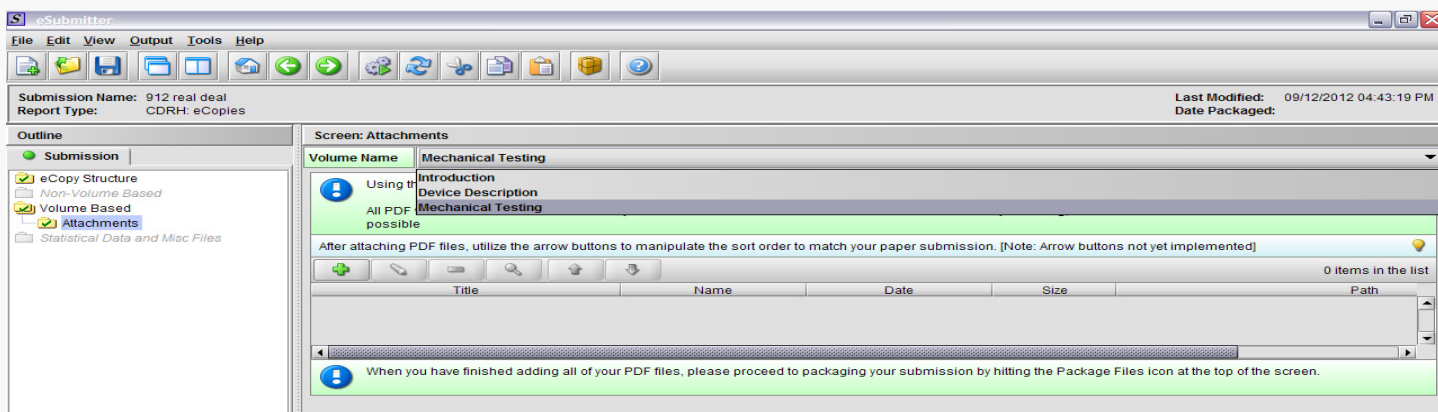
20. To manage the volumes:

- To view the list of volumes, click the List button.
- To delete a volumes, click the List button, choose the volume you want to delete, and click the red “-” button.
- To modify a volume name, click the List button, choose the volume you want to rename, and click the Detail button.
- To reorder volumes, click the blue up and down arrows.

21. Once you have finished adding volumes, click the green arrow key at the top to proceed.

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22. The steps for adding the individual files are the same as for a Non-Volume Based submission with one exception. There is now a Volume Name section with a drop-down feature that allows you to select the volume to which a particular PDF file is to be added. After adding files as per steps #11-16 above, organizing them under the appropriate volume, proceed to packaging your submission. (Step #23)



Packaging the Submission

23. Select the Package Files button on the top bar and select it.



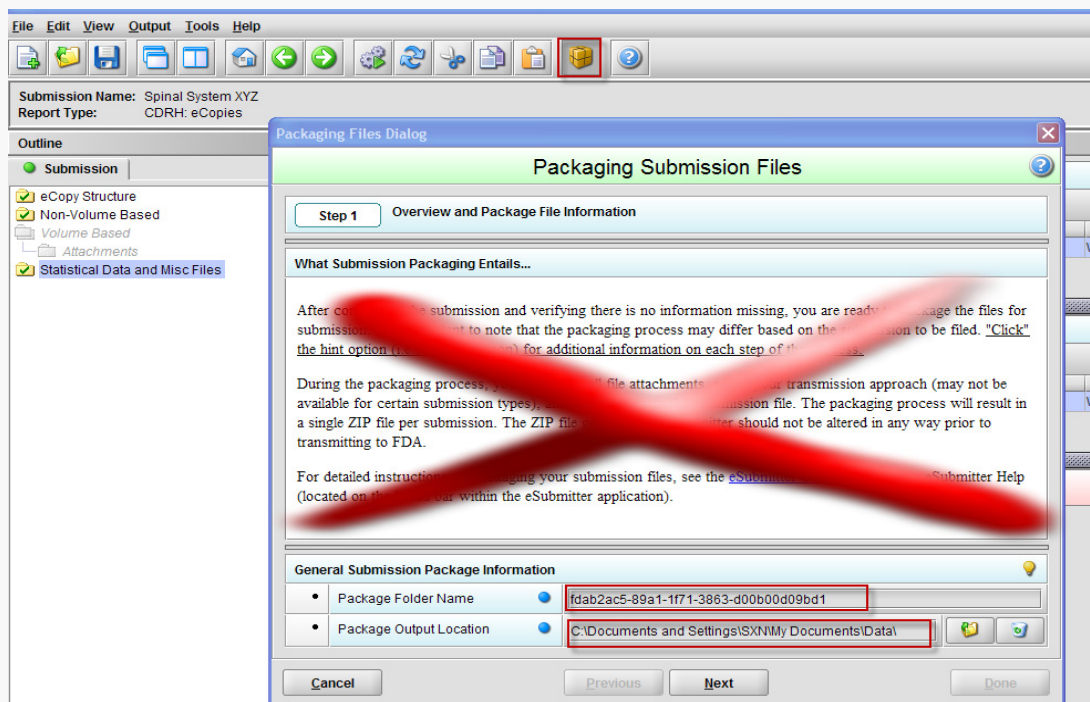
24. There are two outcomes of hitting the **Package Files** button.
- The first outcome is that you receive a small window alerting you of an error. If you do not know what the error is, the window will give you an option to **view a missing data report** that will be displayed to give you details of what is missing to prevent your submission from packaging.
 - The second outcome is that you do not receive an error message. If this is the case, then you will proceed to the packaging steps below.
25. Step 1 of Packaging Submission Files has a description about what it entails. However, none of it pertains to eCopies. **DISREGARD IT.**

Note that the **Package Folder Name** does not match the Descriptive Name provided in Step #6. Nor do you have the option of renaming it at this point. Having said that, once this is saved on your local drive, you can rename it.

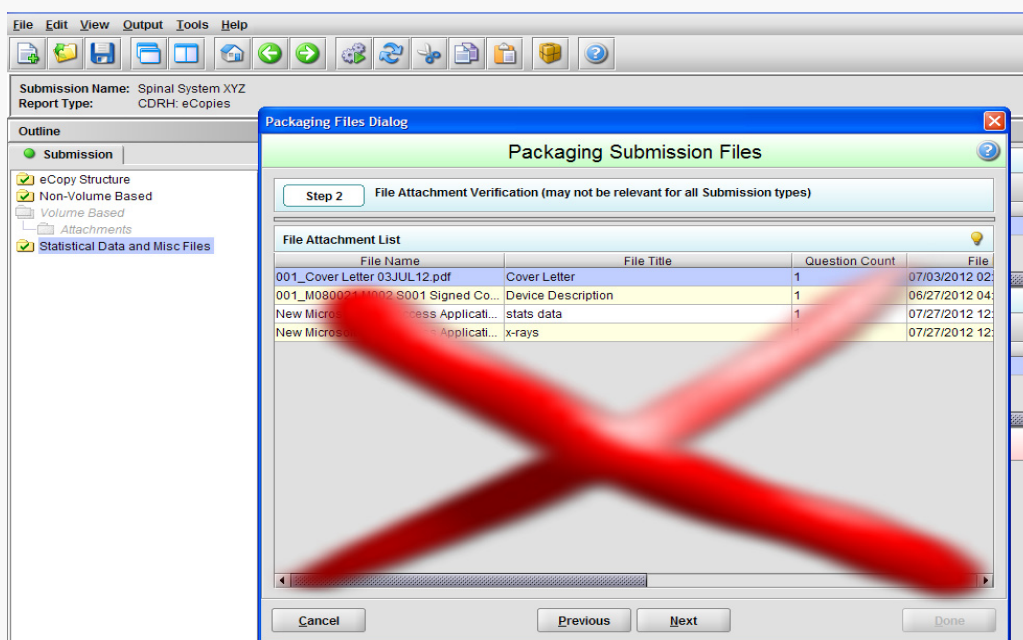
The Package Output Location is what you identified in Step #2. You do have the opportunity to revise this location at this point.

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Click Next to proceed.



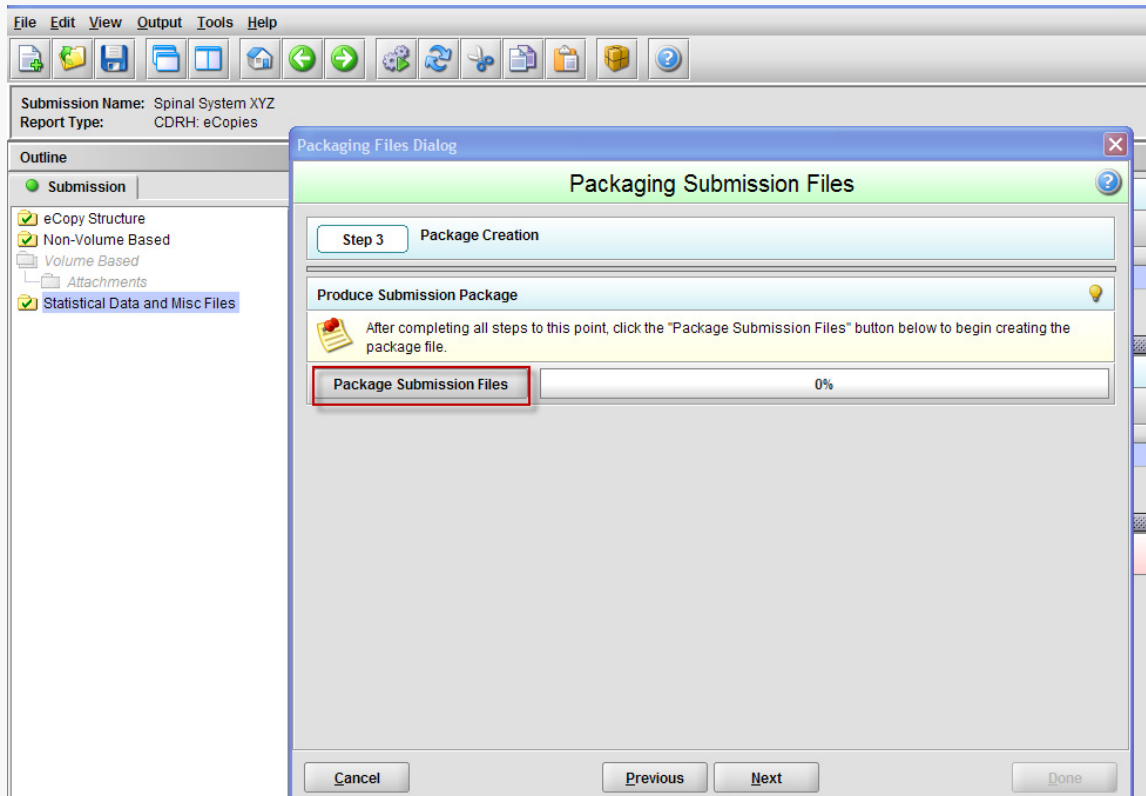
26. Step 2 of Packaging Submission Files shows details about your files, including irrelevant information about question counts that does not pertain to eCopies. **DISREGARD IT.**



Click Next to proceed.

eSubmitter eCopies Quick Reference Guide

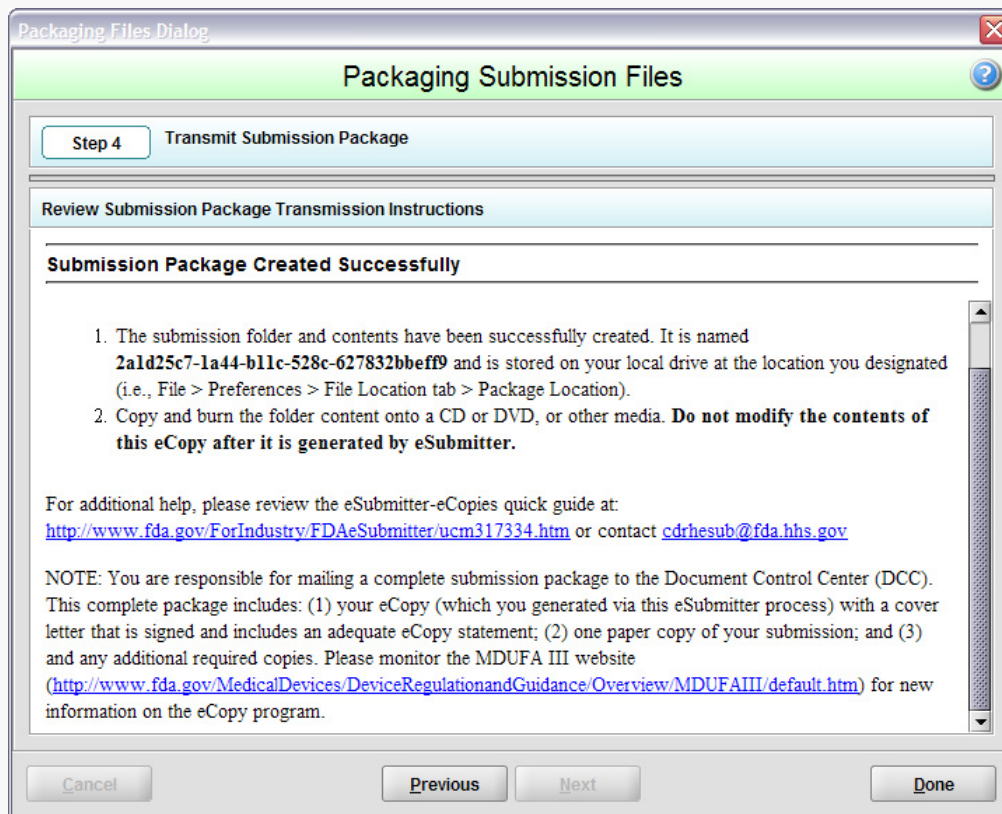
27. Step 3 of Packaging Submission Files allows you to actually create the package. You initiate this by clicking Package Submission Files. When it is done packaging the files, it states "Complete" in the status bar.



Click Next to proceed.

eSubmitter eCopies Quick Reference Guide

28. Step 4 of Packaging Submission Files provides next steps for the applicants.



29. Select **Done** to close the packaging step.

30. You will be returned to the main screen, from there you may choose to File> Exit, New, Open existing or close.

